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No. 89-243

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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27P

QUESTION PRESENTED

Whether the Federal Circuit erred in interpreting the phrase "patented invention" in the patent infringement exemption of 35 U.S.C. § 271(e)(1) to include not only drugs but also medical devices regulated by the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 *et seq.*).

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BRIEF FOR THE RESPONDENT IN OPPOSITION

Respondent, Medtronic, Inc. ("Medtronic"), respectfully opposes the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari and requests that Lilly's petition be denied.[1]

1. Pursuant to Rule 28.1 of the Rules of this Court, Medtronic states that it has no publicly owned parents, subsidiaries, or affiliates. Medtronic does hold a minority interest in Bio-Medicus, Inc. of Minnetonka, MN but does not regard it as an affiliate.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at 872 F.2d 402, and is reprinted in petitioner's appendix ("Pet.App."), at pp.1a-7a. The Court of Appeals denied a petition for panel rehearing on May 31, 1989 (Pet.App. 8a), and issued its judgment as a mandate on June 8, 1989 (Pet.App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing *in banc* on July 18, 1989 (Pet.App. 9a).

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania relating to the scope of 35 U.S.C. § 271(e)(1) is reported at 5 U.S.P.Q.2d 1760 (Pet.App. 15a). The district court also issued a memorandum decision granting a permanent injunction against respondent Medtronic (7 U.S.P.Q.2d 1439; Pet.App. 21a), and a memorandum decision directing that judgment be entered in favor of Petitioner Lilly (7 U.S.P.Q.2d 1447; Pet.App. 41a).

STATUTE INVOLVED

The relevant portions of 35 U.S.C. § 271 provide as follows:

> (a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.
>
> • • •
>
> (e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

STATEMENT OF THE CASE

Lilly brought this action in the United States District Court for the Eastern District of Pennsylvania (Philadelphia) charging Medtronic with infringement of two patents related to implantable medical devices (defibrillators) that automatically shock the heart to correct certain potentially fatal heart rhythms. (Pet.App. 1a-2a). The Medtronic activities charged with infringement were experimental in nature, conducted under the authority of FDA testing regulations. Such testing is a prerequisite to acquiring any FDA approval to commercialize a medical device.

Medical devices of the kind at issue here may not be commercialized in the U.S. prior to receipt of a premarketing approval ("PMA") from the FDA. Application for a PMA generally must be based on clinical experience gained in human trials, and even these trials may not be conducted in the U.S. without permission from the FDA. That permission, known as an Investigational Device Exemption ("IDE"), generally comes with strict controls on such aspects of the testing as the number of devices and the identity of hospitals, physicians, etc., to whom the devices can be supplied for the tests (Veale, Trial Test., Day 13, pp. 40-42).

During the pendency of the litigation, Lilly applied for and obtained a two-year extension of the only remaining patent in issue, U.S. Patent Re. 27,757 ("the '757 patent") (Trial Ex. 623).[2] According to the relevant

2. The other patent in suit, U.S. Patent 3,942,536, is no longer in issue since Medtronic discontinued its testing of the Model 7210 devices charged under that patent in 1985, and has no plans to resume testing of such devices.

statute (35 U.S.C. § 156), the right to, and length of, this extension was based upon the delay that Lilly claimed to have experienced while conducting the FDA-required IDE testing of its own devices (35 U.S.C. § 156(c) and (d); *see also* Trial Ex. 623). The extended '757 patent is now in its 18th year and will expire on October 26, 1990.

To date, Lilly's implantable defibrillators remain the only such devices approved by the FDA for commercialization in the United States (Strain, Trial Test., Day 3, p.60). During the two-year extension period of the '757 patent, Lilly is expected to sell 6,000 to 10,000 units and to collect $100-160 million in sales.[3]

The Medtronic devices accused of infringement are experimental designs expected to lead to the next generation of implantable cardiac treatment devices. Medtronic's latest design, its PCD, is a combination pacer, cardioverter, defibrillator (Pet.App. 24a-25a). The PCD contains all of the features that Lilly's cardiology expert admitted at trial should be in the "ideal implantable device" (Luceri, Trial Test., Day 4, pp.166-67). Medtronic's units are designed to treat most cardiac disturbances painlessly, using low energy electrical impulses to treat all but the most severe conditions (Keimel, Trial Test., Day 7, pp.146-47; Klein, Trial Test., Day 9, pp.34-36, 45). In addition, since they incorporate standard bradycardia (slow heart beat) pacing therapies as well, their use by patients having multiple cardiac problems eliminates the need for implantation of a separate pacer.[4]

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3. Lilly's systems sell for about $16,000 each (Strain, Trial Test., Day 3, p.52). Lilly's projected sales for the extended term are reflected in Trial Ex. 532, as verified by Mr. Strain at trial, Day 3, pp.30-31.

4. The Lilly device, in contrast, treats abnormal heart rhythms by applying very high energy shocks through two electrodes connected directly to the heart (Pet.App. 26a). After experiencing these shocks, 85% of its patients live in "significant fear" of receiving

In the district court, Medtronic moved for a pre-trial ruling that its IDE testing was exempt from any charge of infringement under 35 U.S.C. § 271(e)(1). Judge Ditter denied the motion on December 4, 1987, ruling that the section 271(e)(1) exemption did not apply to medical devices, and entered an order precluding Medtronic's presentation of any evidence at trial concerning the exemption (Pet.App. 15a-20a).[5]

The case was subsequently tried to a jury on Lilly's charges that a total of 31 units, tested over a period of about five years, infringed claims of the patents in suit. The total value of the devices tested by Medtronic was less than $415,000 (Trial Test., Day 18, p.29). Notwithstanding the limited nature of Medtronic's FDA-controlled testing, Lilly contended that the testing gave Medtronic a headstart towards an entry into the commercial marketplace.

Judgment was entered in favor of Lilly on April 21, 1988, including a damage award of a $26.5 million "up-front" payment and a 40% running royalty (Pet.App. 55a). The injunction that was the subject of the interlocutory appeal to the Federal Circuit was entered on the same day, enjoining Medtronic from manufacturing its accused devices or testing them in humans or

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additional shocks, 65% report reduced physical activity, 41% experience a reduction in social interaction, and 41% report sexual abstinence (Luceri, Trial Test., Day 4, pp.156-57). In the opinion of Lilly's own expert, Lilly's automatic implantable defibrillator is "Associated with multiple physical, social and psychological alterations" (*Id.*, at p.157). Moreover, unlike the Medtronic PCD, the Lilly device does not have standard pacing capability, and therefore, any Lilly patient who suffers from either continual or episodic bradycardia would require implantation of a separate pacer, with the additional cost involved and the attendant problems of uncoordinated electrical function between the two devices (*Id.*, at 157-159).

5. Section 271(e) was enacted by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("the 1984 Act"). This law also enacted 35 U.S.C. § 156, under which Lilly received its patent term extension.

animals, and from using data generated from any infringing manufacture, use, or sale of the devices (Injunction Order of April 21, 1988).

On March 29, 1989, the Federal Circuit reversed the district court's holding that section 271(e)(1) did not include medical devices, holding instead that Medtronic could proceed with testing of its devices if solely for purposes reasonably related to the development and submission of information to the FDA (Pet.App. 1a, 7a). The Federal Circuit also remanded the issue of whether Medtronic's earlier testing had been for those purposes (Pet.App. 7a).[6]

Lilly filed a petition for rehearing and suggestion for rehearing *in banc*. The panel denied rehearing on May 31, 1989 (Pet.App. 8a), and the Federal Circuit declined the suggestion for rehearing *in banc* on July 18, 1989 (Pet.App. 9a), with Judge Newman dissenting. The Federal Circuit's mandate issued, after denial of the rehearing, on June 8, 1989, and upon receipt of the mandate, the district court modified its injunction to permit Medtronic to proceed with its IDE testing (Order of June 28, 1989). On July 21, 1989, Lilly filed in this Court an application for an order directing the Federal Circuit to recall and stay its mandate pending the filing of, and final action on, a petition for writ of certiorari. That application was denied by Justice White on July 24, 1989.

Lilly now seeks this Court's review of the Federal Circuit's interlocutory interpretation of the principal patent infringement statute, 35 U.S.C. § 271.

REASONS FOR DENYING CERTIORARI

The decision below is nothing more than an ordinary interpretation of the patent laws by the specialized

6. This application of the Federal Circuit's decision, as well as the resolution of numerous post-trial motions, are currently before the district court. Accordingly, the judgment entered on April 21, 1988, is not final.

appellate court established by Congress for that purpose. The decision is in accord with the plain language of the statute, its legislative history, and the congressional policy behind it. Petitioner's arguments regarding the construction of the statute merely restate positions that a panel of the Federal Circuit unanimously rejected, and that the Federal Circuit declined to rehear *in banc*.[7]

Petitioner contends (Pet. 19) that the decision will slow the development and production of new medical devices by diverting profits from the patentee to competitors who conduct experimental FDA testing. Petitioner's argument erroneously assumes that the courts will give the exemption an overbroad construction and that the FDA itself will provide no effective check against abuse. As yet, however, the record contains no evidence that petitioner's assumptions are correct and no evidence that any of the effects that petitioner forecasts will occur. Indeed, since this case was heard by the Federal Circuit on interlocutory appeal, there is an incomplete record and no determination below even as to whether respondent's activities were within the scope of the infringement exemption. Accordingly, the issues that petitioner seeks to address are not ripe for consideration. In any event, even if petitioner were correct in arguing that a narrower exemption would provide more incentives for the development of new technology, these arguments should be addressed to Congress, not to this Court.

7. *Scripps Found. v. Baxter-Travenol Labs, Inc.*, 7 U.S.P.Q.2d 1562 (D. Del. 1988), does not support petitioner's claim (Pet. 7) that "the only other district court to have considered the issue concluded that section 271(e)(1) is limited to drugs." The *Scripps* case neither considered the issue nor came to the indicated conclusion. The *Scripps* case had nothing to do with medical devices. The dicta relied on by petitioner came in the course of the court's preliminary listing of the few rulings made to that time on section 271(e)(1), and the court was merely repeating, *and citing*, the holding of the district court below.

I. The Federal Circuit Decision Accords With the Plain Language of the Statute, the Legislative History, and Congressional Policy

A. The Plain Meaning of the Statute

The Federal Circuit decision interprets the words of section 271(e)(1) according to their plain and ordinary meaning. The petitioner nevertheless asks this Court to read section 271(e)(1) as though the phrase "drug [or veterinary biological] invention" had been used instead of the much broader term "patented invention."[8]

The ordinary meaning of the unqualified phrase "patented invention" plainly includes medical devices, and an examination of the other paragraphs of section 271 demonstrates that Congress intended the phrase to be given its plain meaning, consistently, throughout. The phrase "patented invention" appears not only in section 271(e)(1), but also in section 271(a), the basic infringement prohibition. Indeed, it is universally agreed that the phrase includes medical devices; petitioner Lilly's infringement claim presumes and depends on that construction. Congress provided no new definition for the phrase when it enacted section 271(e)(1) in 1984 or when it amended the statute in 1988. It must therefore

8. Veterinary biologicals were added to section 271(e)(1) in 1988 by partially amending the statute's original language, which had expressly excluded them. They were also given eligibility for patent extension under section 156. Pub. L. No. 100-670, 102 Stat. 3971 (1988) (hereinafter "the 1988 amendments"). This change was made to the statute during the pendency of the appeal in the Federal Circuit, after briefs were submitted but before the panel decision. The panel noted, however, that the amendments did not change its analysis (Pet.App. 4a). Petitioner relies on the 1988 amendments as clarifying the 1984 intent of Congress with respect to interpretation of "patented invention" (Pet. 9). The amendments, however, provide no such guidance. The significance of Congress' treatment of veterinary biologicals, not only in 1984 but also in 1988, is in its confirmation of the *quid pro quo* aspect of the exemption and statutory extension sections. *See* p.13 n.12, *infra*.

be assumed that "patented invention," when used in section 271(e)(1), has the same meaning as in pre-existing section 271(a). In the absence of a clear legislative intent to the contrary, the same words used in different parts of the same statute are intended to have the same meaning. *Atlantic Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932).

Section 271(e)(1) provides an infringement exemption for a "patented invention" that is made, used, or sold "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." As the Federal Circuit correctly recognized (Pet.App. 5a-6a), the phrase "under a Federal law which regulates" in section 271(e)(1), both as originally enacted and as amended, describes the *law* under which regulation occurs, not the *patented invention* that is regulated. Medical devices are in fact regulated by the principal federal law that regulates drugs, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982 and Supp. III 1985) ("the FFDC Act").[9]

The statutory language does not support petitioner's argument (Pet. 9-10) that the word "drugs" was specifically used by Congress as a clear and limiting definition of the exempted products. If it had intended to give the exemption the limited scope that petitioner favors, Congress would not have used the term "patented invention." In originally enacting, and in amending, section 271(e)(1), Congress twice chose to use the broad term

9. It is not legally significant, as petitioner contends (Pet. 9), that the particular guidelines relating to approvals for drugs and devices are defined in separate sections of the FFDC Act (generally section 335 for drugs and section 360 for devices). Drugs and devices are *regulated* by the *same section* of the FFDC Act – 21 U.S.C. § 331, which prohibits their introduction into commerce without those approvals. 21 U.S.C. §§ 331(d) and (p).

as the description of exempted inventions.[10]

B. The Legislative History Confirms the Plain Meaning of the Statutory Language

The legislative history of section 271(e)(1) is consistent with the plain meaning of the statute. Petitioner correctly observes (Pet. 12) that the legislative history indicates that Congress was particularly concerned with the need to allow FDA-required testing of generic drugs without liability for patent infringement. But regardless of the particular facts that first brought the problem to its attention, Congress legislated in broader terms, dealing with the general problem presented by the interplay between the patent laws and the FFDC Act requirement of lengthy testing before certain regulated products may be sold commercially. On the one hand, Congress recognized that the lengthy period of required noncommercial testing effectively limited the time that the patentee would have exclusive rights to market his invention commercially. H.R. REP. NO. 857, 98th Cong., 2d Sess., Pt. I, 15 (1984). On the other hand, Congress recognized that the requirement of lengthy testing had a second offsetting effect of delaying the entry of competitors into the market beyond the term of the patent if that

10. Petitioner has relied (Pet. 12 n.10) on an amicus brief filed in the Federal Circuit on its behalf by Senator Hatch and Representative Moorhead. It is well settled that the private views of a few legislators, especially those expressed years later in a nonlegislative forum, are entitled to no probative weight in determining the intent of an earlier Congress. *Blanchette v. Connecticut Gen. Ins. Corp.*, 419 U.S. 102, 132 (1974). This rule applies even though the legislators were sponsors of the bill. *Bread PAC v. Federal Election Comm.*, 455 U.S. 577, 582 (1982). In any event, it should be noted that other members of Congress believe that the Federal Circuit's construction of section 271(e)(1) was correct. *See* 135 CONG. REC. S3390 (daily ed. April 5, 1989) (remarks of Sen. DeConcini).

testing were preventable by the patentee until patent expiration. H.R. REP. NO. 857, Pt. I, at 46.

The Federal Circuit's decision in *Roche Prods. Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), which held that competitors have no right to begin the required FDA testing until a patent has expired (thus providing an effective *de facto* extension of the patent during the post-expiration period of the competitor's required testing), prompted Congress to enact remedial legislation addressing these issues and overruling *Roche*. Congress adopted a balanced two-part remedy that included section 271(e)(1). Under a single title of the 1984 Act, Congress (1) enacted 35 U.S.C. § 271(e)(1) to permit FDA-regulated experimental testing by competitors prior to patent expiration in order to eliminate *de facto* extensions, and (2) enacted 35 U.S.C. § 156 authorizing the formal extension of patents to restore the time that a patentee itself had lost to experimental testing on the same product. The House Committee report explained:

> It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.
>
> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged.
>
> • • •
>
> Other sections of Title II [of the 1984 Act] permit the extension of the term of a patent for a definite time

> provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. REP. NO. 857, Pt. I, at 46.

As the Federal Circuit correctly observed (Pet.App. 5a-6a), this legislation was intended to overrule the court's own decision in *Roche*. The Federal Circuit noted that its own holding in *Roche* was not limited to drugs, and that the statute overruling *Roche* could not have been limited to drugs either (Pet.App. 6a, 7a).[11]

Petitioner's argument ignores the fact that Congress intended section 271(e)(1) to be the *quid pro quo* for statutory extension under section 156, that it intended the scope of these changes to be co-extensive, and to include all products – including medical devices – that are subject to FDA-mandated testing under the FFDC Act. Petitioner itself sought and received a formal extension of the patent in suit pursuant to section 156 in order to compensate for the time that it had lost during FDA-mandated testing, yet petitioner asks this Court to limit section 271(e)(1) exclusively to drugs.

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11. The possibility of a lengthy *de facto* extension is at least as great for medical devices of the kind here at issue as it is for generic drugs. Since no expedited approval procedure akin to that for generic drugs exists for medical devices (Veale, Trial Test., Day 13, pp.46-47), their approvals frequently take even longer than those for the drugs. Moreover, the absence of such "piggy-backing" procedures for devices means that there is no incentive merely to copy the older device of the patentee. Accordingly, manufacturers are likely to leap-frog the older device with a more advanced one. (The Medtronic device here, for example, contains beneficial features not found in the Lilly device. Klein, Trial Test., Day 9, pp.42-47, 51-53). To interpret section 271(e)(1) as limited to drugs would require that testing of new medical devices, as opposed to mere copies of existing drugs, would be delayed until after patent expiration. Certainly, the patent laws were intended to provide at least as much incentive to developers of new products as to those who merely copy existing ones.

Petitioner's strained interpretation of section 271(e)(1) would give itself and other patentees of FDA-regulated medical devices the best of both worlds – not only a formal patent extension under section 156, but also a lengthy *de facto* extension resulting from the inability of competitors to begin FDA-mandated testing until the expiration of the patent. This is exactly what Congress intended to prevent by enacting section 156 to provide the only form of extension for patents on such FDA-regulated products: "There should be no other direct or indirect method of extending patent term." H.R. REP. NO. 857, Pt. I, at 46. The Federal Circuit recognized this *quid pro quo* aspect of the legislation (Pet.App. 7a). Petitioner's argument ignores it.[12]

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12. The 1988 amendments confirm the parallel nature and the *quid pro quo* aspect of the patent extension provision of section 156 and the infringement exemption of section 271(e)(1). The original parenthetical exclusion of "new animal drugs and veterinary biological products" in section 271(e)(1) was inserted into the then-pending bill in 1984, contemporaneously with a Judiciary Committee change to section 156 in order to delete those identical products from eligibility for statutory extension. The reason for the insertion had nothing to do with whether the products were or were not human drugs, but rather that those products were to be made the subject of a separate bill. *See* H.R. REP. NO. 857, Pt. I, at 7. It is no coincidence that when the 1988 amendments returned certain of those products to eligibility for section 156 patent extension, the amendments eliminated *de facto* patent extensions for the same products by replacing them within the exemption created by section 271(e)(1).

II. The Record Does Not Demonstrate Any Adverse Consequences As A Result of the Federal Circuit's Interlocutory Decision

A. There is No Basis to Presume That The Interlocutory Decision Will Have Widespread Effect

The importance of this case to the particular parties involved is not in dispute. The decision below has cost petitioner the benefit of its injunction and will negate the disproportionately large damage award that it received. But importance to the parties is not importance to the public in general.[13]

In an effort, nevertheless, to cloak this case with an aura of general significance, petitioner presents (Pet. 16-19) an imaginary parade of horribles led by the decision below. The reality is far more mundane; petitioner's alleged effects have not been demonstrated in the existing record.

Although petitioner contends (Pet. 14-20) that the Federal Circuit's decision will substantially erode patent protection for medical devices, and thereby ultimately chill their further development and production, its arguments rely on a series of unverified assumptions that are either highly questionable or demonstrably incorrect. Many of these arguments are being advanced in this Court for the first time, and accordingly they were not considered by the Federal Circuit, the court with the primary responsibility for the interpretation and administration of the patent laws. None of these arguments justifies review of this case at the present time.

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13. Medtronic has challenged the grossly excessive award, and its challenge is still pending before the trial court. Contrary to petitioner's argument (Pet. 19-20), however, it was the undermining of this particular damage award by the Federal Circuit decision – not general importance of the decision itself to alleged "copiers and infringers" – that caused Medtronic's stock to rise on the decision date.

Petitioner contends (Pet. 19) that the exemption will be judicially interpreted to permit unrestrained infringement by competitors under the guise of clinical trials, and that such competitors could take a substantial share of a patent holder's market during the term of the patent. The record, however, contains no suggestion of how the exemption for medical devices will be construed. To date, no court has passed upon the scope of the exemption as it applies to medical devices. It is precisely this issue that remains to be litigated on remand to the district court, where petitioner is contesting respondent's claim that its experimental use of the devices in question fell within the statutory exemption. There is simply no basis to assume that the lower federal courts will construe the exemption so broadly as to allow wide scale commercialization of competing devices under the guise of IDE testing.

B. Petitioner's Characterization of Device Clinical Trials is Unsupported and Ignores Existing Federal Regulations

Petitioner's general characterization of device clinical trials as rampant commercialization (Pet. 16-20) not only lacks record support, but also ignores the existing regulations of the FDA.

The purpose of the FDA regulations is to ensure that all IDE testing is limited, experimental, and non-commercial. For example, a device manufacturer intending to undertake a clinical investigation must submit, as part of an application for the prerequisite IDE, a detailed investigational plan that describes, among other things, the device, the proposed test procedure, all previous studies of the device, and the proposed investigating physicians and hospitals. 21 C.F.R. §§ 812.20 and 812.25. The regulations generally prohibit medical device manufacturers to profit from the

"sale" of devices during clinical testing. If the manufacturer intends to request reimbursement during the clinical period, the FDA requires a detailed explanation of why the charge "does not constitute commercialization of the device" before it will even permit the testing to begin. 21 C.F.R. § 812.20(8).

Activities that the FDA views to be commercialization, and therefore prohibits, include test marketing of a clinical device; charging investigators a price greater than necessary to recover costs of manufacturing, research, development, and handling; and unduly prolonging any investigation. 21 C.F.R. § 812.7. Generally, when the FDA does approve a clinical test plan, it specifies the medical centers at which the investigational implants may take place and, more importantly, limits the total number of implants (Veale, Trial Test., Day 13, pp.40-42).

Petitioner implicitly assumes that these FDA regulations will not be effective or properly enforced. The policy issues that petitioner seeks to raise would require this Court to undertake a full review of the FDA regulations, the devices and testing procedures that they cover, and the economic effects that they impose in order to assess the effect of the exemption of section 271(e)(1). Yet these issues were not raised in the courts below, and the record, therefore, is totally inadequate for the Court's review. Without that record, it would be inappropriate to adopt petitioner's assumption that these federal regulations will somehow fail to serve their intended purpose.[14]

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14. Petitioner's argument regarding the situation of CAT-scan machines or other major "long-lasting devices" in markets of limited size (Pet. 16, 19) provides an example of its untested theory. Petitioner contends that, in the case of such devices, allowing clinical trials for competitors during the patent term could substantially erode the market for the patented device. This argument, however, ignores the FDA's authority to respond to these special circumstances. For example, the FDA could limit the clinical trials

C. The Only Evidence Of Record Contradicts Petitioner's Arguments

The only evidence now in the record concerns the particular experiences of the parties in this case. Despite petitioner's arguments to the contrary (Pet. 19-20), those experiences demonstrate that respondent's testing had virtually no effect on petitioner's market or patent rights. They indicate in all events that the scope of a competitor's FDA-regulated testing is small in comparison to the patentee's FDA-approved commercialization.

Medtronic's experimentation through the time of trial involved only thirty-one units having a total value of only $415,000 (although not all units were sold and implanted; Pet.App. 24a-25a). At the time that the district court's injunction was entered, Medtronic had an approved IDE limited to 30 additional implants (Trial Ex. 1426), and its expectation then was that it would need 200 further implants over a three-year period, bringing it well beyond the expiration date of Lilly's extended patent, to obtain PMA approval (Veale, Trial Test., Day 13, pp.50-51). By comparison, during the two-year period of its patent extension (which began in October, 1988), petitioner projects sales of over 6,000 devices for revenue of over $100 million. These relative numbers are hardly indicative of the kind of substantial market erosion or destruction of patent rights that petitioner claims requires this Court's immediate intervention.[15]

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to a very few machines, relying on repeated use on many different patients, rather than use of many different machines, to provide a track record for evaluation. That these competing possibilities have not been sorted out below, however, only underscores the unreadiness of the issue for review at this time.

15. Petitioner's position, and the one that Judge Newman took in reliance on it (Pet. 19; Pet.App. 12a n.4) — to the effect that Medtronic expected to realize $11 million in clinical revenues — is based on an early projection (Trial Ex. 139) that petitioner knows (and knew during trial) would never come to pass because Medtronic never received any FDA approval of the scope upon which the projection was based. Petitioner can be expected to complain

III. This Case Presents No Constitutional Issue Requiring Review

Petitioner contends (Pet. 14-16) that section 271(e)(1), as construed by the Federal Circuit, takes a patent holder's rights without just compensation. This issue is spurious and, as a first-time argument, does not warrant review here. The particular constitutional question now raised was neither presented nor considered below. Even if the issue is one that ultimately should be reviewed by this Court, there is no justification for review on the barren record of the present case on interlocutory appeal.

In all events, petitioner's constitutional argument is without merit. It is well settled that *regulation* of rights does not, by itself, constitute a taking. *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979). Moreover, whatever interference with the patent right that petitioner, or any device patentee, might experience as a result of the section 271(e)(1) exemption has been justly compensated for by the grant of statutory extension rights under 35 U.S.C. § 156. The Judiciary Committee considered this theory of "exchange of property interest" and this Court's decision approving that theory, *Penn Central Transp. Corp. v. New York City*, 438 U.S. 104 (1978), in passing on the constitutionality of the original

NOTES *(Continued)*

vehemently, as it has below, about the "damage" that it will sustain, after patent expiration, from experimental testing during the patent life. Even Trial Ex. 139, upon which petitioner relies, however, shows only very low activity by respondent until 1991, after petitioner's patent expires. In all events, neither projections of post-expiration activity, nor the activity itself, is or could be an infringement. Petitioner may justifiably fear the post-expiration market place, when more advanced technology than its own will become available to the public, but it is not entitled to a further *de facto* extension to forestall the "immediate competition" that Congress has said should be encouraged. H.R. REP. NO. 857, Pt. I, at 46. Such an extension would be a direct disincentive to the innovation, for public benefit, that the patent laws are intended to promote.

act. H.R. REP. NO. 857, 98th Cong., 2d Sess., Pt. II, 30 (1984). In the particular case of petitioner, surely the two years of additional exclusivity that it has received — and the $100 million or more that it expects to collect during its extension — are compensation enough to permit limited FDA testing by others in anticipation of the expiration of its extended patent.[16]

IV. Issues of Patent Policy Should Be Addressed to Congress

The policy arguments that petitioner seeks to raise are inextricably tied to the operation of the patent system. Petitioner and others who filed amicus briefs below have already had a chance to address their arguments to the Federal Circuit, the specialized court established by Congress to speak nationwide on matters of patent policy. A unanimous panel of the Federal Circuit issued the ruling in question, and the court as a whole denied rehearing *in banc*, with only one dissent.[17] Moreover, since this case is now on interlocutory appeal, petitioner will have another opportunity to present its arguments to the Federal Circuit on appeal from the

16. Although petitioner raises the further issue that section 271(e)(1) is unconstitutional as applied to a patent that has not been extended (Pet. 18, n.14), petitioner, as a holder of such an extension, lacks standing to raise this issue. *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 474 (1982).

17. In an attempt to suggest an intra-circuit conflict of major importance, petitioner repeatedly relies on the fact and substance of Judge Newman's dissent from the denial of *in banc* reconsideration (Pet. 6, 7, 11, and 18). That dissent, however, was a lone one. But even if there had been some conflict within the lower court, review by this Court is not the proper way to resolve it. *Davis v. United States*, 417 U.S. 333, 340 (1974). It is the appellate court's own *in banc* procedure that has that purpose; the fact that the procedure was declined for use here suggests that there was no conflict at all.

final judgment in the case. The issues that petitioner seeks to raise are squarely within the expertise and jurisdiction of the Federal Circuit.

Nevertheless, even *if* the policy questions raised by petitioner merit further consideration, petitioner should address its arguments to Congress. The history of the legislation involved in this case demonstrates that Congress is concerned with the interplay between the patent laws and the FDA's regulatory scheme. Congress has shown no reluctance to legislate in this area, and even to overrule by statute any decisions with which it has policy-based disagreement.

Indeed, the statute here at issue was adopted within one year of the Federal Circuit's *Roche* decision, which it overruled. Subsequently, in 1988, Congress amended the patent laws to provide for formal extensions of animal drug and veterinary biological patents, and to add those same products to the testing exemption of section 271(e)(1). Legislation was introduced in 1989 to overrule the district court's decision in the present case, but the Federal Circuit's decision made passage of that bill unnecessary.[18]

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18. Recognizing the "legal unfairness with the state of the law" caused by the district court's decision here, Senator DeConcini introduced S. 622 to make it clear that medical devices were within section 271(e)(1). He explained:

> The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medial devices and this must be *clarified.*
>
> • • •
>
> My bill provides the necessary statutory *clarification* for medical devices and reaffirms the purpose behind the 1984 law — to balance the rights of patent holders — who were provided with the ability to secure patent extensions — with the public good of immediate increased competition once the patent expires.

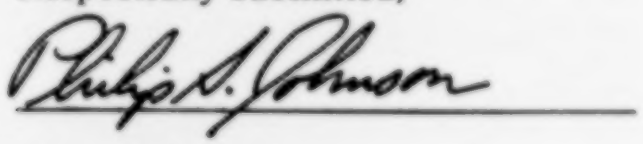
135 CONG. REC. S2861 (daily ed. March 16, 1989) (emphasis added), Pet.App. 58a-60a.

If section 271(e)(1), or the Federal Circuit's decision interpreting it, require further consideration, Congress is the appropriate forum. Indeed, the recent congressional interest in the area and the fact that legislators even now have conflicting views demonstrate that further resolution of these policy questions, if any is needed, should be undertaken by Congress, not by this Court.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted,



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